

REMARKS

In this Amendment, Applicant has amended Claims 19 – 20 and 26 – 28 to overcome the rejections and further specify the embodiments of the present invention. It is respectfully submitted that no new matter has been introduced by the amended claims. All claims are now present for examination and favorable reconsideration is respectfully requested in view of the preceding amendments and the following comments.

REJECTIONS UNDER 35 U.S.C. § 112 FIRST PARAGRAPH:

Claims 19 – 21 and Claims 26 – 28 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to satisfy the enablement requirement and contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is respectfully submitted that the rejection is incorrect because the specification sufficiently describes the present invention as currently amended and enables a person of ordinary skill in the art to practice the claimed invention without undue experimentation.

More specifically, Applicant respectfully submits that the Examiner's understanding of the Hochellinger reference is incorrect. The successful cloning of a mouse with a second generation cloned cell was not obtained by cloning (i.e nuclear transfer) but ONLY by chimera aggregation with a tetraploid embryo. This system (chimera aggregation) does not work in mammals other than the mouse. None of the two references (Wakayama and Hochellinger) have repeated the present invention. Therefore, they have not succeeded.

In addition, the Examiner's argument over primate cloning and undue extrapolation is also irrelevant. The paucity of oocytes available as compared to other animals make cloning more difficult to succeed but efficiency might be the same, if they try as many oocytes as with other animals, they will succeed.

The Examiner's concern is there are two essential features missing from the claims, which were presented in the 1999 Galli paper published in Cloning as essential:

(1) precise optimization of the size of the pipette and (2) use of piezostepper to rupture the oocyte membrane prior to nuclear injection. The Examiner also indicates that, from the teachings of Galli, cytoplasm membrane rupture is critical.

It is respectfully submitted that the Examiner has misunderstood the post-filing-date-published paper and has not understood that one of the documents did show success with second generation cloning. Applicant respectfully submits that the two steps above are NOT essential to make the claimed method work. As shown in the attached Declaration under 37 CFR 1.132 by Dr. Galli, one of the inventors of the present invention, the calf disclosed in the patent application was made without the use of pipette size optimization and use of a piezostepper. In addition, the Declaration also shows that these two steps indicated by the Examiner are NOT essential to make the claimed method work, and a person of ordinary skill in the art is able to practice the present invention based on the disclosure of the application.

In fact, the membranes very often break spontaneously, and without getting through the membrane of the oocyte, a person of ordinary skill in the art is not able to perform nuclear transfer. The piezostepper is just a tool that facilitates the nuclear transfer. Indeed, the embryo that produced Galileo was obtained by direct injection. There are several approaches to microinjection - what is important is the actual "injection", not the way to do it as it is within the purview of a person of ordinary skill in the art. The pipette's role is to disrupt the membrane of the leukocyte and Applicant described in the description that the donors can be transferred intact, with the cell membrane broken, or just as a nucleus. However, it is still possible to succeed without it.

The pending claims have been amended to specify that the donor has to be introduced into the cytoplasm of the enucleated recipient. As pointed out above, a piezostepper is just one option and the donor has to go into the cytoplasm (see the example in the patent application on page 9).

According to MPEP 2164.01(b), as long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. § 112 is satisfied. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Failure to disclose other methods by which the claimed invention may be made does not render a claim invalid under 35 U.S.C. § 112. *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1533, 3 USPQ2d 1737, 1743 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987). Furthermore, under MPEP2164.02, a single working example in the specification for a claimed invention is enough to preclude a rejection which states that nothing is enabled since at least that embodiment would be enabled.

Moreover, not only is it not essential to rupture the cell membrane (see page 3, second paragraph of the specification of the present application, which discusses “optionally” breaking the cell membrane), but there are also many ways to break the cell membrane, other than using a piezostepper. The fact that scientists chose to use this method of rupturing the cell membrane in a paper published after the filing date of the present application simply highlights one way in which this step, if used, can be carried out. With the support of the actual example and the success in the prior art, including those in the cited references, Applicant has provide sufficient disclosure that enable a person of ordinary skill in the art to practice the invention.

Therefore, the rejection under 35 U.S.C. § 112, first paragraph has been overcome. Accordingly, withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 112 SECOND PARAGRAPH:

Claims 19 – 20 and Claims 26 – 28 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is respectfully submitted that the rejections have been overcome by this amendment. More specifically, Claims 19 – 20 and 26 – 28 have been amended according to the suggestion of the Examiner. Claim 21 also includes the amendment by its dependency on Claim 19.

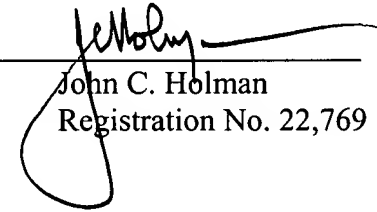
Therefore, the rejection under 35 U.S.C. § 112, second paragraph, has been overcome. Accordingly, withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Having overcome all outstanding grounds of rejection, the application is now in condition for allowance, and prompt action toward that end is respectfully solicited.

Respectfully submitted,

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Enclosure:

Declaration under 37 CFR 1.132